

Remarks

This application has been carefully reviewed in light of the Office Action dated March 30, 2011. Claims 1-3, 5-16, 18-26, and 28-55 are currently in the application, with claims 1-3, 5-15, 29 and 36 having been withdrawn from consideration. Claims 16 and 40 are the independent claims currently under consideration. Reconsideration and further examination are respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 16, 18-20, 23, 24, 26, 28, 31, 35, and 40-55 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 (“Inaba”). Applicant has reviewed the applied reference and respectfully submits that the claimed invention is patentably distinguishable over the applied reference for at least the following reasons.

Independent claim 16 is directed to a discrete film dosage to be taken orally, internally, or epidermally. The discrete film dosage is produced by forming a non-gelatin polymeric film without active ingredients incorporated therein and applying a polar liquid carrier incorporating at least one active ingredient to one or more surfaces of the film. The applied polar liquid carrier is allowed to cure with the film to result in the complete absorption of the at least one active ingredient within the film forming a polymer film product. The noted processes described in Inaba are not seen to produce a discrete film dosage having the same composition or structure as would be produced by the steps recited in independent claim 16.

The Office Action describes Inaba as “making a multilayered dosage system wherein a drug containing film forming organic solvent is applied to an inactive non-gelatin polymeric film and then subsequently dried and cured to form a homogenous multilayered film.” March 30, 2011 Office Action, pg. 3. However, Inaba is silent regarding the transport of the drug contained

in the film forming organic solvent into the inactive non-gelatin polymeric film and, more importantly, is silent regarding the complete absorption of the drug contained in the organic solvent into the inactive non-gelatin polymeric film. In this regard, any transport of the drug into the inactive non-gelatin polymeric film of Inaba would reduce the effectiveness of the inactive non-gelatin polymeric film to act as a drug release controlling layer as intended by Inaba. Accordingly, Inaba arguably teaches away from a composition or structure in which the inactive non-gelatin polymeric film absorbs any of the drug contained in the film forming organic solvent.

The multilayered dosage system described by Inaba produces a drug containing film formed on the surface of an inactive non-gelatin polymeric film. This multilayered structure is seen to be different from the composition and structure of a discrete film dosage in which the active ingredient incorporated into a polar liquid carrier is completely absorbed within an inactive non-gelatin polymeric film to which the polar liquid carrier is applied, as recited in claim 16. An inactive non-gelatin polymeric film that completely absorbs the active ingredient contained in a polar liquid carrier applied to the film does not have the same composition and structure as an inactive non-gelatin polymeric film having a drug containing film formed on one of its surfaces. Should the rejection be maintained, Applicant respectfully requests clarification on the specific structure in the multilayered dosage system described in Inaba that has the same structure and composition as a non-gelatin polymeric film that completely absorbs an active ingredient incorporated into a polar liquid carrier applied to a surface of the non-gelatin polymeric film.

In view of the foregoing remarks, independent claim 16 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 16 are respectfully requested.

Independent claim 40 is directed to a non-gelatin polymeric film where the film includes two or more bands with at least one active ingredient dispersed within a particular band. The non-gelatin polymeric film is a single film with structural homogeneity between the bands. These features are not seen to be disclosed in Inaba.

As discussed above, the multilayered dosage system described in Inaba includes drug containing films formed on inactive non-gelatin polymeric films. Accordingly, the system described in Inaba contains multiple films formed on top of one another and not a single film. Furthermore, Inaba is silent regarding either the drug containing films or the inactive non-gelatin polymeric films containing two or more bands. Should the rejection be maintained, Applicant respectfully requests clarification on where in Inaba either the drug containing film or the inactive non-gelatin polymeric film contain two or more bands.

In view of the foregoing remarks, independent claim 40 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 40 are respectfully requested.

Claims 18-20, 23, 24, 26, 28, 31, 35, and 41-55 are dependent from independent claim 16 described above and, therefore, are believed to be allowable over Inaba for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, the individual consideration of each on its own merits is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 25 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2003/0183643 (“Fagen”). Claims 21, 22, and 37-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2004/0253434 (“Patel”). Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent No. 6,783,768 (“Brown”). Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of Fagen and further in view of U.S. Patent No. 7,112,361 (“Lynn”).

Claims 21, 22, 25, 30, 32-34, and 37-39 are dependent from independent claim 16 discussed above. None of the references applied in the § 103 rejections are seen to disclose or suggest anything to remedy the deficiencies of Inaba discussed above. Therefore, claims 21, 22, 25, 30, 32-34, and 37-39 are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

Conclusion

The absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be other reasons for patentability of any or all claims that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment or cancellation of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment or cancellation.

In view of the foregoing remarks, the claims currently under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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